

### REMARKS

Claims 2-7 and 10 are in this application. Claim 11 has been cancelled. Claim 10 has been amended to read "Method of treating psoriasis wherein a pharmaceutical composition comprising pharmaceutically active amounts of a) L-amino acids serine and isoleucine b) trace elements chromium , tin , selenium, vanadium, and wolfram, and c) folic acid are administered orally to a patient in need thereof."

Claims 2, 3, 4, and 5 have been amended to change "a pharmaceutical" to "the pharmaceutical composition" based on the claim dependency on claim 10.

It is respectfully requested that the amendments to the claims be entered.

The Examiner has rejected claim 11 under 35 USC 112, first paragraph as failing to comply with the written description requirement. Claim 11 was also rejected under 35 USC 112, first paragraph as not being enabled. Applicants respectfully traverse these rejections and consider that this claim is fully supported in the specification, and complies with the written description and enablement requirements of 35 USC 112, first paragraph. However, to expedite prosecution of this application, claim 11 has been cancelled. It is respectfully requested that the rejections of Claim 11 under 35 USC 112, first paragraph be withdrawn.

All rights to file one or more divisional applications to the subject matter of claim 11 and any other subject matter disclosed in the application and not presently, claimed is preserved.

Claims 10-11 were rejected under 35 USC 112, second paragraph as being indefinite. In view of the amendment of claim 10 to include the phrase "a pharmaceutical composition comprising" and cancellation of claim 11, this rejection is moot. It is respectfully requested that this rejection be withdrawn.

Claims 2-7 were rejected under 35 USC 112 is being indefinite. In view of the

amendment of claims 2-5 and claim 10, this rejection is moot and it is respectfully requested that this rejection be withdrawn.

Claims 3-7 and 10 have been rejected under 35 USC 103(a) as being obvious over the combination of Tallberg, et al. in view of Bodaness. Applicants respectfully traverse this rejection.

Tallberg et al. teaches compositions comprising various amino acids and trace elements and that these compositions are useful in bio-immunotherapy. Bio-immunotherapy described in this reference is a biologic treatment using dietary supplements of various amino acids and trace elements and in addition, in some experiments cooked pig brain aimed at biochemical pathways particularly those of the mitochondria. Again, as the Examiner noted, Tallberg does not teach the use of these compositions (or bio-immunotherapy in general) for psoriasis. As explained in the previous response the etiology and pathology of psoriasis is completely different from that of skin cancer. Left untreated many skin cancers will continue to grow and spread leading to the patient's death. This is not the case with psoriasis. There are no tumors, malignant growth or uncontrolled cell division.

There is no suggestion in Bodaness that the use of any amino acid and specifically serine and isoleucine and folic acid would have any place in the treatment of psoriasis. Bodaness is directed to the teaching of administering a peroxide reactive, metal ion containing compound which localizes the tissue to be destroyed after which a peroxide compound is administered which reacts with the metal ion containing compound and forms a product (an oxidant). The formed oxidant is in turn capable of destroying tissue and can be used for treating diseases characterized by accumulation of cells. See column 4, lines 44-46.

In column 7, lines 32 to 55 the function of the metal in the "metal-ion containing compound" is explained as any metal, which is peroxide reacting. In other words, the metal reacts with the peroxide, for example  $H_2O_2$ , and forms oxidant species such as  $OH^\cdot$  radicals. The oxidant species in turn destroy the tissue. The function of the metal-ion is not to treat the

illness. Bodaness teaches that certain metal-ions are peroxide reactive and that oxidant species can destroy tissue.

Examples described in column 4 of Bodaness are metal-porphyrin compound or a metal-porphyrin-antibody compound. Bodaness describes in column 5, the reaction product of the chemical reaction between the peroxide and the tumor-localized metal-ion containing compound is an oxidant species which destroys the cancer.

As explained in the previous response, the Examiner has relied on impermissible hindsight in making this rejection. Given the differences between the prior art, the claims at issue and the level of ordinary skill in the pertinent art, it would not be obvious to administer orally a composition that comprises serine, isoleucine, chromium, tin, selenium, vanadium, wolfram and folic acid to treat psoriasis.

A person skilled in the art setting out to develop a new treatment for psoriasis would have to not only realize that bio-immunotherapy (which previously have been suggested only as a treatment for certain cancers) can be used for psoriasis, but also to find the claimed combination of amino acids and trace-elements are effective to treat psoriasis. Although Bodaness mentions oral administration, the treatment described in the reference is topical. Neither the illness (psoriasis) nor the composition disclosed or suggested in claim 10 is disclosed in Tallberg et al and Bodaness et al alone or in combination. Therefore, current claim 10 is non-obvious over the cited prior art and the Applicant kindly requests that the rejection is withdrawn.

Claim 2 is rejected under 35 USC 103(a) as being unpatentable over Tallberg et al. in view of Bodaness as applied to claims 3-7 and 10 above further in view of Yoneda et al (U.S. Patent 5,997,852).

Tallberg and Bodaness were discussed above.

The combination of these two references with Yoneda also does not make the claims obvious. Yoneda discloses zinc in combination with at least one compound selected from the


group consisting of multivalent unsaturated fatty acids and their esters. Although reference is made to minerals and amino acids in column 3, the multivalent unsaturated fatty acids and their esters are required. Therefore, one of skill in the art would not arbitrarily pick zinc out of this reference.

It is respectfully requested that this rejection be withdrawn.

The term "neurogenic lipids" is still being rejected by the Examiner as indefinite. The Examiner states that the term seems to define the origin of the lipids and not what the lipids are. The Applicant would like to respond that the origin of the lipids is the same as the definition of the lipids. The term "neurogenic lipids" is a collective term for all lipids present in the central nervous system. The term should be compared to other products of natural origin such as orange juice or herbal tea, etc. Therefore, it is not necessary to specify the lipids in order for a skilled person to carry out the invention.

Accordingly, it is submitted that the present application is in condition for allowance and favorable consideration is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'JANET I. CORD', with a horizontal line underneath.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Thomas TALLBERG

Serial No.: 10/588,051

Group No.: 1612

Filed: March 7, 2007

Examiner: HUANG, GIGI G.

For: COMPOSITION, COMPRISING L-SERINE, L-  
ISOLEUCINE, FOLIC ACID AND TRACE ELEMENTS,  
FOR TREATING PSORIASIS

Confirmation Number: 4058

RESPONSE UNDER  
37 C.F.R. 1.116  
EXPEDITED PROCEDURE  
EXAMINING GROUP 1612

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Commissioner for Patents

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AMENDMENT OR RESPONSE AFTER FINAL REJECTION—TRANSMITTAL

CERTIFICATION UNDER 37 C.F.R. 1.8(a) and 1.10\*

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I hereby certify that, on the date shown below, this correspondence is being:

MAILING

- ☐ deposited with the United States Postal Service in an envelope addressed to the Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

37 C.F.R. 1.8(a)

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37 C.F.R. 1.10\*

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EFS-WEB

☒ transmitted electronically

Signature

Janet I. Cord

(type or print name of person certifying)

Date: February 24, 2009

1. Transmitted herewith is an amendment after final rejection (37 C.F.R. 1.116) for this application.

*NOTE: Response to Final Rejection—Avoiding Extension Fees “In patent applications wherein a three month Shortened Statutory Period (SSP) is set for response to a Final Rejection, the response would best be filed within two months of the date of the Office Action. If filed within two months, any Advisory Action mailed after the SSP expires will reset the SSP to expire on the date of the Advisory Action for extension fee purposes, but never more than six months from the date of the Final Rejection.” Notice of Nov. 30, 1990 (1122 O.G. 571 to 591).*

### STATUS

2. The application is qualified as
- ☒ a small entity.
- ☐ other than a small entity.
3. The proceedings herein are for a patent application and the provisions of 37 C.F.R. 1.136 apply for a term of up to six (6) months.

### EXTENSION OF TERM

*NOTE: As to a Supplemental Amendment filed in response to a final office action, the Notice of December 10, 1985 (1061 O.G. 34-35) states:*

*“If a timely response has been filed after a Final Office Action, an extension of time is required to permit filing and/or entry of a Notice of Appeal or filing and/or entry of an additional amendment after expiration of the shortened statutory period unless the timely-filed response placed the application in condition for allowance. Of course, if a Notice of Appeal has been filed within the shortened statutory period, the period has ceased to run.”*

*(complete (a) or (b), as applicable)*

- (a) x Applicant petitions for an extension of time under 37 C.F.R. 1.136  
(fees: 37 C.F.R. 1.17(a)(1)-(4)) for the total number of months checked below:

Extension (months)	Fee for other than small entity	Fee for small entity
<input checked="" type="checkbox"/> one month	\$ 130.00	\$ 65.00
<input type="checkbox"/> two months	\$ 490.00	\$ 245.00
<input type="checkbox"/> three months	\$ 1,100.00	\$ 555.00
<input type="checkbox"/> four months	\$ 1,730.00	\$ 865.00
<input type="checkbox"/> five months	\$ 2,350.00	\$ 1,175.00

Fee \$ 65.00

If additional extension of time is required, please consider this a petition therefor.

*(check and complete the next item, if applicable)*

- ☐ An extension for \_\_\_\_\_ months has already been secured and the fee paid therefor of \$ \_\_\_\_\_ is deducted from the total fee due for the total months of extension now requested.

Extension fee due with this request \$ 65.00

OR

- (b) ☐ Applicant believes that no extension of term is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition and fee for extension of time.

#### FEE FOR CLAIMS

4. The fee for claims (37 C.F.R. 1.16(b)-(d)) has been calculated as shown below:

(Col. 1)		(Col. 2)		(Col. 3)	SMALL ENTITY		OTHER THAN A SMALL ENTITY	
Claims Remaining After Amendment		Highest No. Previously Paid For		Present Extra	Rate	Addit. Fee	OR	Addit. Fee
Total	* Minus	**	=		x \$ 26=	\$		x \$ 52 = \$
Indep.	* Minus	***	=		x \$ 110=	\$		x \$ 220= \$
<input type="checkbox"/> First Presentation of Multiple Dependent Claim					+ \$ 195 =	\$		+ \$ 390 = \$
					Total Addit. Fee	\$	OR	Total Addit. Fee \$

\* If the entry in Col. 1 is less than the entry in Col. 2, write "0" in Col. 3.

\*\* If the "Highest No. Previously Paid For" IN THIS SPACE is less than 20, enter "20".

\*\*\* If the "Highest No. Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest No. Previously Paid For" (Total or Indep.) is the highest number found in the appropriate box in Col. 1 of a prior amendment or the number of claims originally filed.

**WARNING:** See 37 C.F.R. § 1.116.

#### FEE PAYMENT

5. ☐ No additional fee is required.

OR

☐ Total additional fee required is \$ \_\_\_\_\_.

☐ Attached is a check in the sum of \$ \_\_\_\_\_.

☐ Charge Account No. \_\_\_\_\_ the sum of \$ \_\_\_\_\_.

A duplicate of this transmittal is attached.

## FEE DEFICIENCY OR OVERPAYMENT

*NOTE: Where there is a fee deficiency and there is no authorization to charge an account, additional fees are necessary to cover the additional time consumed in making up the original deficiency. If the maximum, six-month period has expired before the deficiency is noted and corrected, the application is held abandoned. In those instances where authorization to charge is included, processing delays are encountered in returning the papers to the PTO Finance Branch in order to apply these charges prior to action on the case. Authorization to charge the deposit account for any fee deficiency should be checked. See the Notice of April 7, 1986, (1065 O.G. 31-33).*

6. ☒ If any additional extension and/or fee is required, charge Account No. 12-0425

AND/OR

- ☒ If any additional fee for claims is required, charge Account No. 12-0425

AND/OR

- ☒ Refund any overpayment to Account No. 12-0425.

Reg. No.: 33778

  
SIGNATURE OF PRACTITIONER

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(type or print name of practitioner)

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